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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,647	07/17/2001	Ramachandran Murali	UPN-3963	3796
7278	7590	11/01/2007	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			CLOW, LORI A	
			ART UNIT	PAPER NUMBER
			1631	
			MAIL DATE	DELIVERY MODE
			11/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/720,647

Applicant(s)

MURALI ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,6-26 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,6-8, 25,26 and 28-31 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 9-24 and 32 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicants' response, filed 10 August 2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1 and 6-26, and 28-32 are currently pending. Claims 2-5 and 27 have been cancelled. Claim 32 is newly added.

It is noted that in the Office Action of 14 August 2003, the previous Examiner stated the following with respect to claims 6-24 that were newly added:

*"2. The addition of new claims 6-24 has been acknowledged.*

*3. Newly submitted claims 9-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: It is noted that the elected subject matter of group I is drawn to a method wherein the limitations for target protein and modifier are unspecified. New claims 9-24 are directed to distinct Species of targets proteins or modifiers, which are not of the elected subject matter by original presentation for prosecution on the merits.*

*4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 9-24 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03."*

It is further noted that Applicant responded on 14 January 2004 with the following:

*"The Examiner contends that previously-submitted claims 9-34 are directed to an invention that is distinct or independent from the originally claimed invention since these claims are drawn to distinct species of target, proteins, or modifiers which were not elected. The Examiner acknowledges that claim 1 is a genus claim and claims 9-24 are*

Art Unit: 1631

*species thereof.*

*In response to this statement, Applicants will withdraw these claims from consideration. However, Applicants request that, should generic claim 1 be allowable following this submission, the claims will be withdrawn from consideration and the Examiner will make species election requirement pursuant to MPEP section 809.02(b), followed by a full action on the merits for the elected species”.*

In the Advisory Action of 11 February 2004, the Examiner acknowledges Applicant's request with the following remark:

*“Upon the allowance of a generic claim 1 from which claim 9-24, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141”.*

Further, Applicant responds on 16 August 2004 as follows:

*“The Examiner contends that previously-submitted claims 9-34 are directed to an invention that is distinct or independent from the originally claimed invention since these claims are drawn to distinct species of target, proteins, or modifiers which were not elected. The Examiner acknowledges that claim 1 is a genus claim and claims 9-24 are species of the genus.*

*In response to this statement, Applicants these claims have been withdrawn. However, should generic claim 1 be found allowable following this submission, it is requested that the Examiner require an election of species pursuant to MPEP section 809.02(b), followed by a full action on the merits for the elected species”.*

As claim 1 is hereby allowable, the following Election of Species requirement, as set forth for claims 9-24 and newly added claim 32 is stated below.

**Election of Species Requirement**

This application contains claims directed to the following patentably distinct species:

**A. Species of Target Protein**, as set forth in claim 9. Applicant is required to choose one from the group consisting of: a membrane-bound protein, a cytosolic protein, a nuclear protein, an enzyme, a cytokine, a lymphokine, a chemokine, an adhesion molecule, a growth factor, and a receptor.

(i) **Subspecies Election for Receptor**, if chosen in claim 9, as recited by claim 12. If Applicant chooses "receptor" as the target protein in claim 9, Applicant must also choose, in claim 12, a particular receptor of the TNF superfamily selected from the group listed in claim 12,

**B. Species of Modifier**, as recited in claim 18. Applicant is required to choose one from the group consisting of: modifier is a protein, modifier is a non-proteinaceous molecule, or modifier is a non-organic molecule.

(i) **Subspecies Election for Protein**, if chosen in claim 18, as recited by claim 19. Applicant is required to choose one from the group consisting of: a membrane-bound protein, a cytosolic protein, a nuclear protein, an enzyme, a cytokine, a lymphokine, a chemokine, an adhesion molecule, a growth factor, and a receptor.

**C. Species of Modifier**, as recited in claim 21. Applicant must choose one modifier selected from the group listed in claim 21.

The species are independent or distinct because each of the species set forth in groups A-C are biochemically different with different functions, locations and activities.

Art Unit: 1631

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 25 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

Art Unit: 1631

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Conclusion**

The outstanding rejections under 35 USC 112, 2<sup>nd</sup> paragraph have been withdrawn in view of the amendments to the claims.

Claims 1, 6-8, 25, 26, and 28-31 are allowable, as the prior art does not teach or fairly suggest the method of identifying a compound that modulates intermolecular interaction between a functionally critical site of a target protein and a modifier comprising the steps set forth. Specifically, the prior art does not teach or suggest identifying a cavity that is a measurable distance from said functionally critical site and calculating the dimensions to identify compounds that modulate.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

**LORI A. CLOW, PH.D.**  
**PRIMARY EXAMINER**



October 26, 2007

Art Unit 1631